DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 804 and 807

[Docket No. 91N-0295]

Medical Devices; Medical Device Distributor Reporting; Opportunity for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comments on the final rule on medical device distributor reporting, which is published elsewhere in this issue of the **Federal Register**. The medical device distributor reporting tentative final rule became final on May 28, 1992, by operation of the Safe Medical Devices Act of 1990 (the SMDA), as amended by the Medical Device Amendments of 1992 (the 1992 amendments). Although not required to do so, FDA realizes that there may be issues not previously considered, such as technical issues on specific provisions, and therefore is providing this additional time for comment. If changes are warranted by comments, FDA will make further changes in the rules.

DATES: Written comments by October 1, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 594-4765.

SUPPLEMENTARY INFORMATION: The SMDA of 1990 (Pub. L. 101-629), which became law on November 28, 1990, included provisions requiring FDA rulemaking to implement distributor reporting requirements. The 1992 amendments (Pub. L. 102-300), which amended certain distributor reporting requirements in the SMDA, became effective on June 16, 1992. Pursuant to the provisions of the SMDA, the regulatory provision relating to distributor reporting in the November 26, 1991, tentative final rule became final by operation of the statute on May 28, 1992. These regulatory provisions were subsequently amended on June 16, 1993, by operation of certain provisions in the 1992 amendments. The final rule on distributor reporting published elsewhere in this issue of the **Federal Register** explains the distributor reporting and statutory deadline provisions in more detail.

FDA has already provided opportunities for public comment on the proposal that preceded the rule published today as required by the Administrative Procedure Act. FDA is issuing a final rule based on consideration of these comments to the November 26, 1991, proposed tentative final rule in the near future. Until that time, the rule that is published elsewhere in this issue of the **Federal Register** will govern the reporting requirements for distributors. Although FDA is allowing additional comments on this rule, this action is in no way required by the Administrative Procedure Act. FDA is not interested in receiving comments that it has already received and considered. Although the agency does not believe that any public purpose would be served by reopening for further comment at this time the issues already addressed in the final rule being published, FDA recognizes that in any rulemaking there may be technical issues involving specific provisions that have not been considered. Therefore, the agency is providing 30 days for comment on this final rule on such issues. Comments should be identified with the docket number found in brackets in the heading of this document. FDA will publish additional changes in the final rule if comments bring to FDA's attention an issue, not already considered, that warrants revision.

Under 21 CFR 10.40(e), an opportunity for comment on this final rule is being provided. Interested persons may, on or before October 1, 1993, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This document is issued under the authority of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, and 374) and under authority delegated to the Commissioner of Food and Drugs.

Dated: August 25, 1993

Michael R. Taylor,

Deputy Commissioner for Policy.

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BILLING CODE 4160-01-F

[Docket No. 91N-0295]

21 CFR Parts 804 and 807

Medical Devices; Medical Device Distributor Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; notification of status under the Safe Medical Devices Act; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the tentative final rule on medical device distributor reporting that appeared in the **Federal Register** of November 26, 1991 (56 FR 60024), is now a final rule by operation of law. This final rule requires distributors to submit reports to FDA and to manufacturers, of deaths, serious illnesses, and serious injuries related to medical devices and to submit reports to manufacturers of certain malfunctions that may cause a death, serious illness, or serious injury, if the malfunction were to recur. The final rule also changes the reporting standard for certain distributors that are importers, and changes the definition of the term "serious injury" to conform to a recent statutory amendment. In issuing this final rule, FDA is announcing that the tentative final rule relating to adverse event reporting requirements for distributors, including importers, has the status of a final rule, as of May 28, 1992, by operation of law under the Safe Medical Devices Act of 1990 (the SMDA), as amended by the Medical Device Amendments of 1992 (the 1992 amendments), and is setting forth the regulations reflecting those requirements. FDA is also amending the regulations, based on consideration of comments on the November 26, 1991, tentative final rule, to require distributors to register their facilities and to list their devices with FDA.

DATES: Part 804 is effective May 28, 1992; the amendments to part 807 are effective October 1, 1993.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ-306), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-594-1156.

SUPPLEMENTARY INFORMATION:

I. Background

The current regulatory framework for medical device reporting requirements is the result of four statutes:

(1) The Federal Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. 321–394) (the act);

(2) The Medical Device Amendments of 1976 (Pub. L. 94–295) (the 1976 amendments), which amended the act to establish the first comprehensive framework for the regulation of medical devices;

(3) The SMDA (Pub. L. 101–629), which amended the act to correct noted problems with the implementation and enforcement of the 1976 amendments; and

(4) The Medical Device Amendments of 1992 (Pub. L. 102–300) (the 1992 amendments), which amended certain provisions of the act relating to devices.

Section 519 of the act (21 U.S.C. 360i), as added by the 1976 amendments, authorized FDA to issue regulations to require manufacturers, importers, and distributors to maintain such records, make such reports, and provide such information to FDA as may reasonably be necessary to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. The legislative history of the 1976 amendments reflects clear congressional intent to permit FDA to require, under the authority of section 519 of the act, device manufacturers, importers, and distributors to report to FDA product defects and adverse effects of the firms' devices. (See H. Rept. 853, 94th Cong., 2d sess. 23 (1976).) Among other things, section 519 of the act states that any reporting requirement established under the authority of that section: (1) May not be unduly burdensome (considering the cost of compliance and the need for the requirement); (2) shall state the purpose for any required report or information and identify to the fullest extent practicable such report or information; (3) may not, except in certain circumstances, require the disclosure of a patient's identity; and (4) may not, except in certain circumstances, require the manufacturer, distributor, or importer of a class I device to maintain records, or to submit information not in its possession, unless such report or information is necessary to determine whether a device is misbranded or adulterated. The House Report cautions, however, that these limitations "should not be construed * * * as limiting the Secretary's authority to obtain information needed to insure that the public is protected from potentially hazardous devices." Id. at 24.

In discussing the notification provisions of section 518 of the act (21 U.S.C. 360h), the House Report, the principal legislative document on the amendments, states:

> The notification provision is similar to, and to some extent patterned after, comparable authority contained in the National Traffic and Motor Vehicle Safety Act of 1966, the Radiation Control for Health and Safety Act of 1968, and the Consumer Product Safety Act of 1972. These statutes also include requirements that manufacturers provide notification of defects in their products to appropriate Federal agencies. The Committee determined that a comparable provision in new section 518(a) with respect to devices would be unnecessary since the Secretary could require the reporting of such information under the recordkeeping and reporting authority provided in new section 519 of the Act.

(H. Rept. 853, supra, at 21.)

In its discussion of section 519 of the act, the House Report lists examples of reasonable reporting requirements, including reports of defects, adverse reactions, and patient injuries. That Congress intended FDA to use its authority under section 519 of the act to protect the public from potentially hazardous devices, as well as devices with confirmed hazards, is also clear from the legislative history. Id. at 24.

In the Federal Register of September 14, 1984 (49 FR 36348), FDA issued the current medical device reporting (MDR) regulations (21 CFR part 803). The regulations require manufacturers and importers of medical devices, including diagnostic devices, to report to FDA whenever the manufacturer or importer becomes aware of information that reasonably suggests that one of its marketed devices: (1) May have caused or contributed to a death or serious injury, or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Since the enactment of the 1976 amendments, Congress has focused considerable attention on FDA's implementation and enforcement of the act with respect to medical devices. During this time, the General Accounting Office (GAO), Office of Technology Assessment (OTA), and Office of Inspector General of the Department of Health and Human Services (OIG) conducted investigations and issued reports on problems associated with significant weaknesses in FDA's information gathering ability and its followup mechanisms for information that is received. S. Rept. 513, 101st Cong., 2d sess. 15 (1990). A GAO study, for example, noted that although FDA has received more than a seven-fold increase in reports associated with device-related problems since the promulgation of the MDR regulation, serious under reporting of device-related, reportable events exists. GAO also noted that many firms are unaware of their obligation to report device-related deaths, injuries, and malfunctions to FDA, and that device-related deaths in hospitals are rarely reported to either FDA or the manufacturer. A GAO followup study in 1989 concluded that despite implementation of the MDR regulations, serious shortcomings exist.

Congress concluded from its own hearings and investigations and from its review of the GAO, OTA, and OIG investigations and reports that the 1976 amendments were not always adequate to protect the public health. (H. Rept. 808, 101st Cong., 2d sess. 13–14 (1990), S. Rept. 513, 101st Cong., 2d sess. 13–16 (1990).) On November 28, 1990, to correct these problems, the SMDA was signed into law to amend the medical device provisions of the act.

The SMDA added section 519(b)(1) to the act (21 U.S.C. 360i(b)(1)) to require that certain device user facilities report deaths related to medical devices to FDA and to the manufacturer, if known. FDA may also, by regulation, include outpatient diagnostic facilities in this requirement.

Although since 1976, under section 519 of the act, FDA has had the authority to require distributors to report adverse effects and deficiencies of devices, the agency until this point had not implemented this authority. However, the legislative history of the SMDA reflects Congress' belief that FDA must require distributors to make such reports because distributors may be the first to recognize possible device problems. (See H. Rept. 808, 101st Cong., 2d sess. 22–23 (1990).) Accordingly, the SMDA added section 519(a)(6) to the act to require distributors to report to FDA adverse effects and deficiencies of devices, and to submit copies of these reports to manufacturers. Id.

The SMDA also added section 519(d) to the act requiring reporting manufacturers and distributors to certify to FDA the number of reports submitted in a year or the fact that no such reports have been submitted to the agency. This requirement was directly in response to a GAO finding that certification would increase the efficiency of the MDR. (See S. Rept. 513, 101st Cong., 2d sess. 26 (1990).)

The SMDA directed FDA to issue a proposal to implement distributor

reporting and recordkeeping requirements within 9 months of the enactment. (See section 3(c)(1)(A) of the SMDA.) The SMDA provides that the proposed rule relating to distributor reporting would become final 18 months after the enactment of the SMDA, May 28, 1992, if a final rule was not promulgated by that date.

On November 26, 1991 (56 FR 60024), under the authority of sections 502, 510, 519, 520, 701, and 704 of the act (21 U.S.C. 352, 360, 360i, 360j, 371, and 374), FDA issued a proposed rule designated as a "tentative final rule" that would implement the reporting requirements of the SMDA relating to manufacturers, distributors, and user facilities. This tentative final rule would require device user facilities and distributors, including importers, to submit reports to FDA and/or the manufacturers, of deaths, serious illnesses, and serious injuries related to medical devices. This tentative final rule also proposed to amend existing reporting requirements in 21 CFR part 803 for manufacturers to conform them with the proposed reporting requirements for user facilities and distributors. Further, it proposed to require distributors and manufacturers to report certain malfunctions that may cause a death, serious illness, or serious injury. Under the tentative final rule and pursuant to section 519(d) of the act, distributors and manufacturers would also be required to certify annually the number of reportable events submitted during the previous calendar year or the fact that no such reports were received.

The tentative final rule also proposed to amend 21 CFR part 807 to require distributors to register and list with FDA, pursuant to section 510 of the act. This exercise of authority is necessary to implement the new adverse event reporting requirements for distributors.

II. Comments

In the **Federal Register** of January 24, 1992 (57 FR 2861), FDA announced that it was extending the comment period for the tentative final rule until February 26, 1992. FDA received over 300 comments on the tentative final rule. At present, FDA is still considering the comments on the tentative final rule relating to manufacturer, distributor, and user facility adverse event reporting and has not issued a final rule that is based on consideration of those comments. Because FDA did not promulgate a final rule for distributor reporting by May 28, 1992, however, the provisions in the tentative final rule relating to distributor adverse event reporting automatically became the final rule on that date pursuant to section 3(c) of the SMDA.

On June 16, 1992, subsequent to the statutory provision making the tentative final rule with respect to distributors automatically final, additional statutory provisions further amending distributor reporting requirements became law (the 1992 amendments). Section 5(a) of the 1992 amendments adopts a single standard to determine when injuries caused by devices must be reported to FDA: A manufacturer, importer, or user facility is required to report a device-related, adverse event to FDA when information reasonably suggests that a device * * * "may have caused or contributed to * * * death or * * * serious injury."

Section 5(a) of the 1992 amendments also adopts a single definition for the types of injuries that manufacturers, importers, distributors, and user facilities must report. This definition requires reporting of an injury that is life threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. This definition differs from the previous statutory definition of "serious injury" that is applied to device user facilities in that it deletes the requirement that an injury must require immediate intervention to preclude permanent impairment or damage in order to qualify as a reportable injury.

The effective date of the amendments made by section 5(a) of the 1992 amendments is either 1 year from the date of the enactment of the 1992 amendments, or on the effective date of the FDA regulations implementing such amendments, whichever occurs first. Because FDA has not issued regulations implementing the 1992 amendments, the provisions of the 1992 amendments became effective by operation of law on June 16, 1993. See section 5(b) of the 1992 amendments.

FDA is issuing this rule and notifying the public pursuant to the directive of section 3(c)(2) of the SMDA that distributor adverse event reporting requirements proposed in the November 26, 1991, tentative final rule are now final. This final rule reflects certain changes from the November 26, 1991, tentative final rule that conform to the 1992 amendments that became effective on June 16, 1993. In addition, FDA is issuing this final rule, based on consideration of comments received in response to the tentative final rule, requiring distributors to register their establishments and list their devices.

At a later date, FDA intends to amend the final distributor reporting regulation and to issue final regulations governing manufacturer and user facility reporting to reflect the changes to the reporting requirements for user facilities and manufacturers made by the 1992 amendments. These future final regulations will also reflect consideration of comments relating to adverse event reporting submitted in response to the November 26, 1991, tentative final rule.

Under the provisions of this final rule that became effective by operation of law, distributors, other than importers, are required to submit a report to FDA, and a copy of such report to the manufacturer, containing the information required by new § 804.28, as soon as practicable, but not later than 10 working days after the distributor becomes aware of information from any source, that reasonably suggests that there is a probability that a device marketed by the distributor has caused or contributed to a death, serious illness, or serious injury. Distributors, other than importers, must also submit reports to the manufacturer containing the information required by new § 804.28, as soon as practicable, but not later than 10 working days after the distributor becomes aware of information, from any source, that one of the devices marketed by the distributor has malfunctioned and such information reasonably suggests there is a probability that the device or any other device marketed by the distributor would cause a death, serious illness, or serious injury, if the malfunction were to recur.

Distributors that are importers are subject to a slightly different standard as required by the 1992 amendments. Specifically, an importer must submit a report to FDA, and a copy of such report to the manufacturer, containing the information required by new § 804.28, as soon as practicable, but not later than 10 working days after the importer becomes aware of information from any source that one of the devices marketed by the importer may have caused or contributed to a death or serious injury. Importers are also required to submit reports to the manufacturer containing the information required under new § 804.28 as soon as practicable but not later than 10 working days after the importer becomes aware of information, from any source, that reasonably suggests, that one of its marketed devices has malfunctioned and such device or a similar device marketed by the importer would be likely to cause or to contribute to a death or serious injury if the malfunction were to recur.

The agency is aware that many distributors have limited capabilities to conduct followup investigations or failure analyses, or both. It is also unlikely that device user facilities are accustomed to providing patient or adverse device experience followup information to distributors. Consequently, a distributor's role in the MDR process is one of an intermediary who forwards data from user facilities, or any other source, to FDA and the manufacturer. Distributors are not required to investigate the cause of adverse device events; rather, they are required to assess whether or not a reportable event has occurred. This responsibility includes review and verification of data that they receive and supplying information that is within a distributor's control to FDA or the manufacturer, or both.

On June 3, 1993, FDA announced the availability of a new form for adverse event reports from manufacturers, user facilities, and distributors in the **Federal Register** (58 FR 31596). This single form replaces certain existing reporting forms and is to be used for reporting adverse events and product problems with devices as well as medications and other products regulated by the agency. This form will be required on the date that the final rule, based on comments to the November 26, 1991, tentative final rule, for user facility, manufacturer, and distributor reporting requirements becomes effective, or November 30, 1993, whichever occurs later. In the meantime, distributors are encouraged to submit reports on these forms. These forms may be obtained from the Division of Small Manufacturers Assistance, (HFZ–220), Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. Bulk copies of the form may be obtained from the Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

The final rule also requires that distributors certify annually to FDA either the number of MDR's during the previous annual reporting period, or that the distributor did not receive any reportable events during this period. Annual certification will follow the same schedule as registration. Distributors must also establish files of information related to MDR's and retain the files for 2 years from the date the report or information was submitted to FDA or the manufacturer or for a period of time equivalent to the design and expected life of the device, whichever is longer.

In order to implement the new adverse event reporting requirements, FDA is now issuing a final rule, based on comments on the tentative final rule, requiring distributors to register and list. The tentative final rule proposed revising current § 807.22(c) to require distributors who initiate or develop specifications for a device and distributors who repackage or relabel a device to submit a listing form and maintain an historical file (§ 807.22(c)(1) and (c)(2)). Such persons, however, are already required to list under current § 807.20(a) and (c). Therefore, in the final regulation, FDA is deleting proposed registration and listing requirements in § 807.22(c)(1) and (c)(2) for persons who initiate or develop device specifications or who repackage or relabel because these requirements would be duplicative of the existing requirements under current § 807.20(a) and (c). Accordingly, because such persons are already required to list, the new listing requirements for distributors add new requirements only for persons who do not initiate or develop the specifications for the device or repackage or relabel the device. Although these distributors are not required to submit a listing form, they must submit, for each device, listing information including the name and address of the manufacturer. Such distributors shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are distributors. The final regulations states that certain entities that manufacture devices according to another parties specifications or that sterilize devices are exempt from registration and listing requirements.

FDA received several comments relating to the distributor registration and listing requirements proposed in the tentative final rule. They are summarized below:

A. § 807.3(g)—Definitions

1. Some comments stated that clarification was needed for the difference between manufacturers and distributors.

A distributor, as defined in § 807.3(g), is any person who furthers the marketing of a device, but does not repackage, or otherwise change the container, wrapper, or labeling of the device package. A manufacturer includes any person who repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device. To the extent that manufacturers are also engaged in the distribution process, they are only required to report as manufacturers.

B. § 807.20—Who Must Register and Submit a Device List

2. Two comments argued that FDA does not have authority to require distributors to register and list.

FDA does not agree with these comments. The plain language of the act provides FDA with explicit authority to require distributors to register and list. Section 510(c) of the act states that:

> "[e]very person upon first engaging in the manufacture, preparation, *propagation*, compounding, or processing of * * * a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment."

(Emphasis added).

This language makes it clear that FDA has authority to require distributors to register because they are engaged in the "propagation" of devices. Although neither the statute nor the legislative history define the term "propagation," this term is defined in Webster's Ninth New Collegiate Dictionary as "the spreading of something abroad or into new regions." (Merriam Co. 1990). Certainly, persons who distribute medical devices in interstate commerce are "spreading * * * something * * * into new regions" and, therefore, are persons who propagate medical devices within the meaning of the statute. Moreover, the language of section 510(c) of the act demonstrates that Congress intended to provide FDA with broad authority to require persons who are engaged in a wide range of activities with respect to medical devices to register their devices. Accordingly, Congress not only authorized FDA to require persons to register who are engaged in the manufacture of devices, but also authorized FDA to require persons to register who are engaged in the "preparation, propagation, compounding, or processing" of medical devices. These words taken together, or individually, provide FDA with authority to require registration of any person who is involved with the distribution of medical devices.

The statute also provides clear authority to require distributors to list their devices. FDA's authority to require distributors to list derives directly from the agency's authority to require distributors to register. Specifically, section 510(j)(1) of the act requires that "[e]very person who registers under subsection (b), (c), or (d) shall, at the time of registration under any such subsection, file with the Secretary a list of all * * * devices * * * which are being

manufactured, prepared, propagated, compounded, or processed by him for commercial distribution." Accordingly, because FDA has authority to require distributors, as propagators of devices, to register, FDA also has authority to require distributors to list their devices pursuant to section 510(j)(1) of the act.

3. One comment stated that distributor listing information is duplicative of manufacturer listing information and that therefore, distributors should not be required to establish costly procedures to obtain and provide listing information. One comment suggested that distributors of devices be exempted from the registration and listing requirements. Another comment suggested that distributors of domestic devices be exempt form registering.

FDA does not agree with the comments that require distributors to list provides information that duplicates manufacturer listing information nor does FDA agree that distributors in general or distributors of domestic devices should be exempt from these requirements. Obtaining listing information from both manufacturers and distributors allows FDA to have an accurate up-to-date inventory of medical devices that is necessary to implement the agency's regulatory and enforcement authorities. Manufacturer listing information alone does not provide FDA with information about who distributes products. Distributor registration and listing information is necessary because it will provide additional information that will help FDA in enforcement of distributor medical device reporting requirements, and in implementing product recalls and notifications under section 518 of the act. Accordingly, the final rule requires distributors to provide registration and listing information.

4. Two comments requested that multisite distributors be allowed the option of decentralized registration. Another comment stated that multisite distributors should be allowed the option to choose which location would be the reporting location and FDA contact location for purposes of FDA registration and reporting.

FDA agrees that multisite distributors should have the option of registering only a central location or each location. Under the final regulation, a multisite distributor who chooses to file registration for only one central location, must register only the primary or principal place of business establishment located in the United States where the MDR complaint files are maintained.

C. § 807.21—Times for Establishment Registrationand Device Listing

5. One comment requested clarification as to when the distributor registration requirement is effective.

On June 15, 1992, FDA issued a letter notifying distributors that registration requirements were effective on July 15, 1992. FDA has reconsidered this position and is extending the deadline for submission of registration requirements to October 1, 1993. Distributors will also be required to list their devices as of October 1, 1993.

D. § 807.22—How and Where to Register and List

6. One comment suggested that this section be revised, so that there is a distinction between a repackager and a distributor.

The agency disagrees that this section should be modified because the definition does make a distinction between distributors and repackagers. Under the definition any person who changes the package or label is not a distributor. Repackagers or relabelers are considered manufacturers, and they must register and list as such.

E. § 807.65—Exemptions for Device Establishments

7. Two comments asked whether dental supply stores must register.

Under section 807.65(e) dental supply stores that dispense or sell devices in the regular course of business at the retail level are exempt from registration requirements.

The codified text below contains only those adverse event reporting requirements from the November 26, 1991, tentative final rule, as amended by the 1992 amendments, which apply to distributors, since only the distributor reporting requirements have become final. Incorporation of the distributor requirements from the tentative final rule into part 803 as it is currently written is not feasible because of organizational changes in the text. Therefore, the distributor reporting requirements are being codified separately at this time in new 21 CFR part 804. When the final rule is published in its entirety, the distributor requirements will be removed from part 804, and all of the reporting requirements for manufacturers, device user facilities and distributors, including importers, will be merged into 21 CFR part 803.

III. Paperwork Reduction Act of 1980

The recordkeeping and reporting requirements for medical device distributors, including importers, were submitted to the Office of Management and Budget (OMB) for review as part of the tentative final rule that was published in the Federal Register of November 26, 1991, that proposed the adverse event reporting requirements for manufacturers, distributors and user facilities. These recordkeeping and reporting requirements have been approved by OMB under control number 0910–0059 "Medical Devices: Medical Device Reporting, User Facility Reporting, Distributor Reporting, Manufacturer Reporting, Certification, Registration," and are in conformance with the Paperwork Reduction Act of 1980 (44 U.S.C. ch. 35).

OMB has also approved the new adverse event reporting form for use by distributors, as well as user facilities and manufacturers under control number 0910–0291 "MedWatch: FDA's Medical Products Reporting Program." The availability of the form was announced by the agency in the Federal Register of June 3, 1993 (58 FR 31596), and the form is in conformance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. ch. 35).

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect or the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

In conjunction with the agency's issuance of the tentative final rule proposing to require device user facilities and distributors, including importers, to submit reports of certain adverse events to FDA and to manufacturers (56 FR 60024, November 26, 1991), FDA placed on file at the Dockets Management Branch a copy of the agency's threshold assessment of the economic effects of this rule.FDA has carefully examined the economic impact of this action in accordance with the requirements of Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). The agency concludes that the rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act. A copy of the document supporting this determination is on file at the Dockets Management Branch (address above) and may be seen in that office between

9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 804

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, new part 804 is added and part 807 is amended as follows:

1. New part 804 is added to read as follows:

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

Subpart A—General Provisions

Sec.
804.1 Scope.
804.3 Definitions.
804.9 Public availability of reports.

Subpart B—Reports and Records

804.25 Reports by distributors.
804.27 Where to submit a report.
804.28 Reporting form.
804.30 Annual certification.
804.31 Additional requirements.
804.32 Supplemental information.
804.33 Alternative reporting requirements.
804.34 Written MDR procedures.
804.35 Files.

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

Subpart A—General Provisions

§ 804.1 Scope.

(a) FDA is requiring medical device distributors to report deaths, serious illnesses, and serious injuries that are attributed to medical devices. Distributors are also required to report certain device malfunctions and to submit a report to FDA annually certifying the number of medical device reports filed during the preceding year, or that no reports were filed. These reports enable FDA to protect the public health by helping to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use. In addition, device distributors are required to establish and maintain complaint files or incident files as described in § 804.35, and to permit any authorized FDA employee at all reasonable times to have access to, and to copy and verify, the records contained in this file. This part supplements, and does not supersede, other provisions of this subchapter, including the provisions of part 820 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 804.3 Definitions.

(a) Act means the Federal Food, Drug, and Cosmetic Act.

(b) and (c) [Reserved]

(d) *Distributor* means any person, including any person who imports a device into the United States, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under § 804.3(k).

(e) *Distributor Report Number* means the number that uniquely identifies each report submitted by a distributor. Distributors who receive or submit reports shall use their seven digit FDA registration number, calendar year that the report is received, and a sequence number. For example, the complete number will appear as follows: 1234567–1991–0001. Distributor report numbers shall also be required on FDA form 3500A.

(f) *FDA* means the Food and Drug Administration.

(g) [Reserved]

(h) *Incident files* are those files containing documents or other information, which are related to adverse events that may have been caused by a device.

(i) *Information that reasonably suggests that there is a probability that a device has caused or contributed to a death or serious injury or serious illness* means information, including professional, scientific, or medical facts, observations, or opinions, which would cause a reasonable person to believe that a device caused or contributed to a death, serious injury, or serious illness.

(j) *Malfunction* means the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised.

(k) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device chemically, physically, biologically, or by other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture, to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(l) *MDR* means medical device report.

(m) *MDR reportable event* means:

(1) The event for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that a device has caused or contributed to a death, serious illness, or serious injury; or

(2) The event for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(3) A malfunction, for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that the device, if the malfunction were to recur, would be likely to cause or contribute to a death, serious illness, or serious injury; or

(4) A malfunction, for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device has malfunctioned and that such device or a similar device would be likely to cause or contribute

to a death or serious injury if the malfunction were to recur.

(n) through (p) [Reserved]

(q) *Permanent* means nonreversible impairment or damage.

(r) *Probability, probable, or probably* means, for purposes of this section, that a person would have reason to believe, based upon an analysis of the event and device, that the device has caused or contributed to an adverse event. This term does not signify statistical probability.

(s) *A remedial action* is any recall, repair, modification, adjustment, relabeling, destruction, inspection, patient monitoring, notification, or any other action relating to a device that is initiated by a distributor, in response to information that it receives or otherwise becomes aware of, that reasonably suggests that one of its marketed devices has caused or contributed to an MDR reportable event.

(t) *Serious illness* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to the body structure; or

(3) Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(u) *Serious injury* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(v) [Reserved]

(w) *Work day* means Monday through Friday excluding Federal holidays. Federal holidays include New Year's Day, Martin Luther King Jr.'s Birthday, Presidents' Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

(x) Any term defined in section 201 of the act shall have the same definition unless otherwise defined in this part.

§ 804.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and

(2) Any personnel, medical, and similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter; provided, that, except for the information under § 20.61 of this chapter, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

Subpart B—Reports and Records

§ 804.25 Reports by distributors.

(a)(1) A distributor, other than an importer, shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that there is a probability that a device marketed by the distributor has caused or contributed to a death, serious illness, or serious injury.

(2) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b)(1) A distributor, other than an importer, shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the distributor has malfunctioned and such information reasonably suggests that there is a probability that the device or any other device marketed by the distributor would cause a death, serious illness, or serious injury, if the malfunction were to recur.

(2) An importer shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

§ 804.27 Where to submit a report.

(a) Any telephone report required under this part shall be provided to 301–427–7500.

(b) Any facsimile report required under this part shall be provided to 301–881–6670.

(c) Any written report or additional information required under this part shall be submitted to:

Food and Drug Administration,
Center for Devices and Radiological Health,
Distributor Report,
P.O. Box 3002,
Rockville, MD 20847–3002.

§ 804.28 Reporting form.

(a) Each distributor that submits a report on an MDR reportable event shall complete and submit the applicable portions of FDA form 3500A in so far as the information is known or should be known to the distributor, and submit it to FDA, and to the manufacturer as required by § 804.25.

(b) Each distributor shall submit the information requested on FDA form 3500A, including:

(1) Identification of the source of the report.

(i) Type of source that reported the event to thedistributor (e.g., lay user owner; lay user lessee, hospital, nursing home, outpatient diagnostic facility, outpatient treatment facility, ambulatory surgical facility);

(ii) Distributor report number;

(iii) Name, address, and telephone number of the reporting distributor and the source that reported the event to the distributor; and

(iv) Name of the manufacturer of the device.

(2) Date information.

(i) The date of the occurrence of the event;

(ii) The date the source that reported the event to the distributor became aware of the event;

(iii) The date the event was reported to the manufacturer and/or FDA; and

(iv) The date of this report.

(3) The type of MDR reportable event, e.g., death, serious illness, serious

injury, or malfunction, and whether an imminent hazard was involved;

(4) Patient information including age, sex, diagnosis, and medical status immediately prior to the event and after the event;

(5) Device information including brand and labeled name, generic name, model number or catalog number or other identifying numbers, serial number or lot number, purchase date, expected shelf life/expiration date (if applicable), whether the device was labeled for single use, and date of implant (if applicable);

(6) Maintenance/service information data including the last date of service performed on the device, where service was performed, whether service documentation is available, and whether service was in accordance with the service schedule;

(7) Whether the device is available for evaluation and, if not, the disposition of the device;

(8) Description of the event.

(i) Who was operating or using the device when the eventoccurred;

(ii) Whether the device was being used as labeled or as otherwise intended;

(iii) The location of the event;

(iv) Whether there was multi-patient involvement, and if so, how many patients were involved;

(v) A list of any other devices whose performance may have contributed to the event and their manufacturers, and the results of any analysis or evaluation with respect to such device (or a statement of why no analysis or evaluation was performed); and

(vi) A complete description of the event including, but not limited to, what happened, how the device was involved, the nature of the problem, patient followup/treatment required, and any environmental conditions that may have influenced the event.

(9) The results of any analysis of the device and the event, including:

(i) The method of evaluation or an explanation of why no evaluation was necessary or possible;

(ii) The results and conclusions of the evaluation;

(iii) The corrective actions taken; and

(iv) The degree of certainty concerning whether the device caused or contributed to the reported event;

(10) The name, title, address, telephone number, and signature of the person who prepared the report.

804.30 Annual certification.

Distributors required to report under this section shall submit a certification report to FDA by the date designated for annual registration for the firm in § 807.21 of this chapter. This date will cover the period ending 1 month before the month of the scheduled date of mailing as indicated in § 807.21(a). The report will contain the following information:

(a) The name, address, telephone number, and FDA registration number of the distributor;

(b) A statement certifying that:

(1) The distributor listed in paragraph (a) of this section has filed reports under this section during the previous 12-month period and all MDR reportable events have been submitted to FDA and/or to the appropriate manufacturer. The report will also include the number of death, serious injury or serious illness reports that were submitted to FDA, and the number of malfunction reports that were submitted to manufacturers; or

(2) The distributor listed in paragraph (a) of this section did not receive any reportable events during the previous 12-month period.

(c) The name, address, title, telephone number, and signature of the individual making the certification for the firm. This person must be a responsible person designated by the firm.

§ 804.31 Additional requirements.

Requests for additional information. If FDA determines that the protection of the public health requires information in addition to that included in the medical device reports submitted to FDA under this part, the distributor shall, upon FDA's request, submit such additional information. Any request by FDA under this section shall state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information.

§ 804.32 Supplemental information.

(a) Only one MDR is required under this part if the distributor becomes aware, from more than one source, of information concerning the same patient and the same event.

(b) An MDR that would otherwise be required under this section is not required by the distributor if:

(1) The distributor determines that the information received is erroneous in that a death, serious injury, serious illness, or the malfunction did not occur; or

(2) The distributor determines that the information received is erroneous in that the device that is the subject of the information was distributed by another distributor. A distributor shall forward to FDA any report that is erroneously sent to the distributor, with a cover letter explaining that the product in question is not distributed by that firm.

(c) A report or information submitted by a distributor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, the establishment submitting the report, or employees thereof, caused or contributed to a death, serious injury, serious illness, or malfunction. A distributor need not admit, and may deny, that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a death or serious injury, serious illness, or malfunction.

§ 804.33 Alternative reporting requirements.

(a) Distributors may request exemptions from any or all of the reporting requirements in this part. These requests are required to be in writing and to include both the information necessary to identify the firm and device and an explanation why the request is justified.

(b) FDA may grant a distributor, in writing, an exemption from any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. In granting such exemptions, FDA may impose other reporting requirements to ensure the protection of public health and safety. FDA may also authorize the use of alternative reporting media such as magnetic tape or disk, in lieu of FDA forms.

(c) FDA may revoke alternative reporting options, in writing, if FDA determines that protection of the public health justifies a return to the requirements as stated in this part.

§ 804.34 Written MDR procedures.

Device distributors shall maintain and implement written MDR procedures in the following areas:

(a) Training and education programs informing employees about obligations under this section, including how to identify and report MDR reportable events;

(b) Internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, a standardized review process/procedure for determining when an event meets the criteria for reporting under this part, and timely transmission of complete MDR's to FDA and/or manufacturers; and

(c) Documentation and recordkeeping requirements for:

(1) Information that may be the subject of an MDR;

(2) All MDR's and information submitted to FDA and manufacturers;

(3) Information that facilitates the submission of certification reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

§ 804.35 Files.

(a) A device distributor shall establish a device complaint file in accordance with § 820.198 of this chapter and maintain a record of any information, including any written or oral communication, received by the distributor concerning all events that were considered for possible reporting under this part. Device incident records shall be prominently identified as such and shall be filed by device. The file shall also contain a copy of any MDR along with any additional information submitted to FDA under this part. A distributor shall maintain records that document the submission of copies of MDR's to manufacturers.

(b) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date that the report or additional information is submitted to FDA under § 804.25, or for a period of time equivalent to the design and expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the report or the additional information.

(c) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

2. The authority citation for 21 CFR part 807 is revised to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

3. Part 807 is amended by revising the part heading to read as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

4. Section 807.3 is amended by revising paragraphs (d)(2) and (g), by amending paragraph (e)(3) by removing the word "and" after the semicolon at the end of the paragraph, by amending paragraph (e)(4) by removing the period at the end of the paragraph and by adding in its place "; and", and by adding new paragraph (e)(5) to read as follows:

§ 807.3 Definitions.

* * * * *

(d) * * *

(2) Distribution of domestic or imported devices; or

* * * * *

(e) * * *

(5) The annual certification of medical device reports required by § 804.30 of this chapter or forwarding the certification form to the person designated by the firm as responsible for the certification.

* * * * *

(g) Distributor means any person who furthers the marketing of a device from the original place of manufacture, whether domestic or imported, to the person who makes final delivery or sale to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

* * * * *

5. Section 807.20 is amended by revising paragraph (a)(4) and by adding new paragraphs (c) and (d) to read as follows:

§ 807.20 Who must register and submit a device list.

(a) * * *

(4) Distributors;

* * * * *

(c) Distributors of domestic or imported devices must register and fulfill their listing obligations as described in § 807.22(c) of this part. Distributors with multiple sites may submit one registration for all sites or submit a registration for each site. If a multisite distributor chooses to file one registration, the registration must be from the principal business establishment which maintains the MDR complaint files.

(d) Registration and listing requirements shall not pertain to any person who:

(1) Manufacturers devices for another party who both initiated the specifications and commercially distributes the device;

(2) Sterilizes devices on a contract basis for other registered facilities who commercially distribute the devices.

* * * * *

6. Section 807.21 is revised to read as follows:

§ 807.21 Times for establishment registration and device listing.

(a) An owner or operator of an establishment who has not previously entered into an operation defined in § 807.20 shall register within 30 days after entering into such an operation and submit device listing information at that time. An owner or operator of an establishment shall update its registration information annually within 30 days after receiving registration forms from FDA. FDA will mail form FDA-2891a to the owners or operators of registered establishments according to a schedule based on the first letter of the name of the owner or operator. The schedule is as follows:

First letter of owner or operator name	Date FDA will mail forms
A, B, C, D, E	March.
F, G, H, I, J, K, L, M .	June.
N, O, P, Q, R	August.
S, T, U, V, W, X, Y, Z	November.

(b) Owners or operators of all registered establishments shall update their device listing information every June and December or, at their discretion, at the time the change occurs.

7. Section 807.22 is amended by revising paragraphs (a) and (c) to read as follows:

§ 807.22 How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on form FDA-2891 (Initial Registration of Device Establishment). Forms are obtainable upon request from the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, or from the Food and Drug Administration (FDA) district offices. Subsequent annual registration shall be accomplished on form FDA-2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under § 807.35(a). The forms will be mailed to the owner or operators of all establishments in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to

the above-designated address within 30 days after receipt from FDA.

* * * * *

(c) The listing obligations of the distributor are satisfied as follows:

(1) The distributor is not required to submit a form FDA-2892 for those devices for which such distributor did not initiate or develop the specifications for the device or repackage or relabel the device. However, the distributor shall submit, for each device, the name and address of the manufacturer. Distributors shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the distributors; and

(2) The distributor shall update the information required by paragraphs (c)(1) of this section at the intervals specified in § 807.30.

8. Section 807.25 is amended by revising paragraph (b) to read as follows:

§ 807.25 Information required or requested for establishment registration and device listing.

* * * * *

(b) The owner or operator shall identify the device activities of the establishment such as manufacturing, repackaging, or distributing devices.

* * * * *

9. Section 807.65 is amended by revising paragraph (e) and by removing and reserving paragraph (g) to read as follows:

§ 807.65 Exemptions for device establishments.

* * * * *

(e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.

* * * * *

Dated: August 25, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

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